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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/065,278

09/30/2002

Jeffrey C. Leung

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07/27/2004

MOORE & VAN ALLEN, PLLC  
2200 W MAIN STREET  
SUITE 800  
DURHAM, NC 27705

EXAMINER

DAWSON, GLENN K

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/065,278

Applicant(s)

LEUNG ET AL.

Examiner

Glenn K Dawson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 23-33 and 36 is/are rejected.
- 7) ☒ Claim(s) 17-22, 34 and 35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12-16-02, 7-10-03</u> . | 6) <input type="checkbox"/> Other: _____  |

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the claimed attachment mechanisms of shrink-wrap tubing, channel wrapping and eyelet threading, and the underside of the overlapping barb being derived from part of the top side of the overlapped barb, must be shown or the features canceled from the claims. No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,2,5-12,14,16,23-33 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative, obvious over either Leung, et al.-6599310 or Leung, et al.-2004/0030354, (in view of Granger-5123911).

Both Leung references disclose a suture needle/suture combination having a needle attached to a barbed suture by swaging or through the use of a heat shrink-wrap tube. The barbs are staggered, helical or randomly arranged about the suture. The suture can be bio-absorbable or non-absorbable. The figures show the proximal end of the needle about the same diameter of the suture. Additionally, the claimed needle diameter could be the diameter of the needle at the sharpened tip, which would be smaller in diameter than the suture material. However, in the event that neither of these readings of the disclosure is found to adequately disclose the claimed diameter ratio, Granger clearly discloses in col. 7 lines 13-21, that it was known to attach sutures of equal diameter to the suturing needle. Also shown in fig. 12 is that the diameter of the

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needle shank portion 12 is smaller than the diameter of the suture, thus reading on claim 7.

It therefore would have been obvious to have made the suture diameter at least as large as that of the needle, in order to provide a strong suture and one which easily traverses through the tissue.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1,2,5-8,10-13,15,16 and 23-33 are rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative, obvious over Buncke-5931855 (in view of Granger-'911).

Buncke discloses a suture/suture needle combination having the suture swaged to the needle. The suture is bio-absorbable or non-absorbable. The suture has barbs in a staggered or spiral arrangement.

The figures show the proximal end of the needle about the same diameter of the suture. Additionally, the claimed needle diameter could be the diameter of the needle at

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the sharpened tip, which would be smaller in diameter than the suture material.

However, in the event that neither of these readings of the disclosure is found to adequately disclose the claimed diameter ratio, Granger clearly discloses in col. 7 lines 13-21, that it was known to attach sutures of equal diameter to the suturing needle. Also shown in fig. 12 is that the diameter of the needle shank portion 12 is smaller than the diameter of the suture, thus reading on claim 7.

It therefore would have been obvious to have made the suture diameter at least as large as that of the needle, in order to provide a strong suture and one which easily traverses through the tissue.

Claims 1,2,5-7,12,13,15,23-33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcamo-3123077 in view of Granger-'911.

Alcamo discloses a barbed suture having overlapping, spirally arranged, irregularly or regularly spaced about the suture. However, the attachment to a suturing needle and the ratio of the diameters are not disclosed.

Granger discloses in col. 7 lines 13-21, that it was known to attach sutures of equal diameter to the suturing needle. Also shown in fig. 12 is that the diameter of the needle shank portion 12 is smaller than the diameter of the suture, thus reading on claim 7.

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It therefore would have been obvious to have made the suture diameter at least as large as that of the needle, in order to provide a strong suture and one which easily traverses through the tissue.

Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcamo-'077 in view of Granger-'911 as applied to the claims above, and further in view of Leung-'310.

Alcamo as modified by Granger makes obvious the invention as claimed with the exception of the suture material. Leung discloses the claimed suture material. It would have been obvious to have made the suture of Alcamo out of the suture material as disclosed by Leung, as it would allow for either a suture which need not be removed, or one which is stronger and longer lasting to ensure proper healing in certain operations.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung-'310 (or Leung, et al.-'354) in view of Granger-'911, as applied to the claims above, and further in view of Granger-'013.

Leung as modified by Granger makes obvious the invention as claimed with the exception of the coating on the needle. Granger discloses that it was known to place a coating of silicone on a surgical needle. It would have been obvious to have placed a silicone coating on the needle of Leung, as this facilitates the passage of the needle through the tissue.



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Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granger-'911 in view of Alcamo-'077, as applied to the claims above, and further in view of Granger-'013.

Granger as modified by Alcamo makes obvious the invention as claimed with the exception of the coating on the needle. Granger discloses that it was known to place a coating of silicone on a surgical needle. It would have been obvious to have placed a silicone coating on the needle of Leung, as this facilitates the passage of the needle through the tissue.

#### ***Allowable Subject Matter***

Claims 17-22,43 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on 703-308-0858. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Glenn K Dawson  
Primary Examiner  
Art Unit 3731

Gkd  
22 July 2004